REMARKS

Rejections under 35 U.S.C. § 103

Claims 6, 12, 13 and 23 – 25 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combined disclosures of **Klein et al.** (US 2,870,198) in view of **Spires** (US 4,394,377).

This rejection is based on an erroneous reading of **Klein et al.** The examiner stated that "[t]he '198 patent discloses a method of making crystalline choline salts comprising reacting trimethylamine, gaseous ethylene oxide and anhydrous acids at temperatures from 0 – 5 °C …." This statement is erroneous. In fact, **Klein et al.** disclose a multi-step process. In the process disclosed in **Klein et al.**, trimethylamine and ethylene oxide are not reacted in the presence of an acid, and the temperature of the overall process exceeds 5°C.

Klein et al. disclose a first step of reacting ethylene oxide, trimethylamine and water to completion. (See: Column 1, indicated lines 35 – 37; Column 2, l indicated ines 45 – 50; Column 2, indicated lines 60 – 65; Column 2, indicated lines 65 – 72; Example 1: Column 3, indicated lines 45 – 52; Example 2: Column 3, indicated line 74 – Column 4, indicated line 7; and Example 3: Column 3, indicated lines 19 – 26). **Klein et al.** disclose that "temperatures of from 0°C to 100°C can suitably be employed"[1] in this step of the process. Please note, however, that only Example 1 discloses that this step was conducted at "a temperature of about 0°C to 10°C."[2] Example 2 discloses that this step was conducted "at a temperature of 15°C - 20°C."[3] Example 3 discloses that this step was conducted "at a temperature of 16°C - 30°C."[4]

Klein et al. disclose a second step of adding a "hot alcoholic solution of [a particular] acid."[5] **Klein et al.** disclose that "if desired … [this hot alcoholic solution of the acid] may be prepared using an alcohol which has been heated to or near its reflux

[1] **Klein et al.** (US 2,870,198) at column 2, indicated lines 50 – 55.
[2] **Klein et al.** (US 2,870,198) at column 3, indicated lines 50 – 53.
[3] **Klein et al.** (US 2,870,198) at column 4, indicated lines 3 – 4.
[4] **Klein et al.** (US 2,870,198) at column 4, indicated lines 23 – 24.
[5] **Klein et al.** (US 2,870,198) at column 3, indicated line 35.

temperature in order to give a higher concentration of the acid in the solvent."[6] **Klein et al.** discloses that when this "hot alcoholic solution of the acid" is added to the mixture obtained as a product of the reaction in the first step, the temperature of the overall mixture rises. **Klein et al.** does not specify precisely how high the temperature rises, however, it is clear that the temperature rises higher than 5°C, because **Klein et al.** disclose a third step, wherein "[the] reaction mixture is cooled to about 5°C, or below." In Example 1, "[t]his mixture was ... cooled with agitation to 5°C." Examples 2 and 3 are irrelevant, in this respect, because as discussed above the temperatures utilized in their first steps exceeded the claimed range.

Due to the examiner's erroneous reading of the **Klein et al.** reference, "applicant [was] reminded that absent a showing of new or unexpected results the selection of any order of processing steps is prima facie obvious."[7] It is respectfully submitted that a proper reading of the **Klein et al.** reference makes it clear that more than an adjustment in the order of processing steps disclosed in the **Klein et al.** reference was required to arrive at the present invention. Indeed, an entirely different process is presented in the present application. **Klein et al.** does not disclose reacting ascorbic acid with trimethylamine and ethylene oxide, and carrying out the reaction in a temperature range from 0°C to 5°C. As discussed above, **Klein et al.** disclose reacting trimethylamine and ethylene oxide to completion in a temperature range from 0°C to 100°C and subsequently adding a hot alcoholic solution of an acid (as admitted by the examiner, **Klein et al.** "is silent to the inclusion of ascorbic acid"[8]). First, **Klein et al.** disclose that the addition of this "hot alcoholic solution of an acid" increases the temperature of the overall mixture to above 5°C. Second, the subsequent addition of "hot alcoholic solution of an acid" to the product of a completed reaction of trimethylamine and ethylene oxide is not equivalent to reacting ascorbic acid with trimethylamine and ethylene oxide as required by the claims. Indeed, **Klein et al.** in no way describes reacting any acid (let alone ascorbic acid) with trimethylamine and ethylene oxide. **Klein et al.** only discloses adding a hot alcoholic solution of an acid, "which is to be used in forming the desired salt of [the] choline"[9]

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[6] **Klein et al.** (US 2,870,198) at column 3, indicated lines 15 – 20.
[7] Page 3, line 7 – 8 of the present Office action.
[8] Page 2, line 22 of the present Office action.
[9] **Klein et al.** (US 2,870,198) at column 2, indicated lines 71 – 72.

which has already been produced.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The examiner has not pointed to a teaching, suggestion, or motivation for a person of ordinary skill in the art at the time the invention was made to make the requisite modifications to the process disclosed by **Klein et al**. More specifically, the examiner has not pointed to a teaching, suggestion or motivation for a person of ordinary skill in the art at the time the invention was made to ignore **Klein et al.**'s teaching of "first reacting trimethylamine with ethylene oxide and water in an aqueous alcohol solution containing one mole of water ... [and subsequently] treating the resulting reaction mixture with whatever acid is to be used for producing the choline salt,"[10] and instead reacting ascorbic acid with trimethylamine and ethylene oxide in a single step. Similarly, the examiner has not pointed to a teaching, suggestion or motivation for a person of ordinary skill in the art at the time the invention was made to carry out a single step reaction of ascorbic acid with trimethylamine and ethylene oxide at a temperature range from 0°C to 5°C, especially when **Klein et al**. recommended "using a hot alcoholic solution of the acid,"[11] which raises the temperature of the mixture above 5°C. The **Spires** reference was cited only to allege that "[i]t would have been obvious to substitute any organic salt into the reaction of the '198 patent in order to product [*sic*] pure and stable choline salts." The **Spires** reference, therefore, does not compensate for these shortcomings of the **Klein et al**. reference.

Likewise, the examiner has not demonstrated that a person of ordinary skill in the art would have had a reasonable expectation of success upon making the modifications to **Klein et al**. that would have been necessary to arrive at the process of the present

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[10] **Klein et al**. (US 2,870,198) at column 1, indicated lines 35 – 40.

[11] **Klein et al**. (US 2,870,198) at column 3, indicated line 35. **Klein et al**. disclose that this solution "may be prepared using an alcohol which has been heated to or near its reflux temperature in order to give a higher concentration of the acid in the solvent"(Column 3, indicated lines 15 – 20).

invention. The **Spires** reference was cited only to allege that "[i]t would have been obvious to substitute any organic salt into the reaction of the '198 patent in order to product [*sic*] pure and stable choline salts." The **Spires** reference, therefore, does not compensate for this shortcoming of the **Klein et al.** reference.

Additionally, a proper reading of the **Klein et al.** reference shows that the reference does not teach or suggest all of the claim limitations. More specifically:

1. **Klein et al.**'s process does not produce crystalline choline ascorbate,
2. **Klein et al.**'s process does not react ascorbic acid with trimethylamine and ethylene oxide,
3. **Klein et al.**'s process does not carry out a reaction of ascorbic acid with trimethylamine and ethylene oxide at a temperature range from 0°C to 5°C, and
4. **Klein et al.**'s process results in the production of choline itself, instead of producing crystalline choline ascorbate directly.
5. As admitted by the examiner, **Klein et al.** "is silent to the inclusion of ascorbic acid."[12]

Reading the **Klein et al.** reference in view of the **Spires** reference does not compensate for these shortcomings, and in fact demonstrates that choline ascorbate prepared according to a process substantially identical to the process of **Klein et al.**[13] results not in the production of crystalline choline ascorbate, but in the production of a heavy viscous oil.

For at least these reason, it is respectfully submitted that the present invention is not obvious over **Klein et al.** in view of **Spires**. Favorable action is solicited.

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[12] Page 2, line 22 of the present Office action.

[13] **Spires** references **Hoffmann** (US 2,823,166), which discloses a process substantially identical to **Klein et al.** and results in the production of a heavy viscous oil. A more detailed discussion of the **Hoffmann** reference is found in the Reply of August 9, 2006.